Remarks

Applicants have amended the specification to correct the formalities identified by the Examiner. Applicants have also canceled withdrawn claims 11, 13, 17, 19, and 22. No new matter has been added. Claims 23-42 are pending.

I. Objections to the Specification

A. Hyperlinks

The Examiner has objected to the specification for including browser-executable hyperlinks. *See* Paper No. 10, page 2.

In response, Applicants have amended paragraphs 13 and 157 to remove the "http://", thus eliminating the browse-executable code while retaining the listed web addresses. Accordingly, Applicants believe that the instant objection has been obviated and should be reconsidered and withdrawn.

B. Incorporation by Reference

The Examiner has objected to the specification for incorporating accession numbers by reference. *See* Paper No. 10, page 2. In particular, the Examiner notes that the source of the accession numbers is not provided, and asserts that the referenced materials are subject to change.

In response, Applicants have amended paragraph 786 to remove the incorporation by reference statement and to indicate that the accession numbers refer to the GenBank® database, as noted by the Examiner. Accordingly, Applicants believe that the instant objection has been obviated and should be reconsidered and withdrawn.

II. Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 26-27 and 29-42 under 35 U.S.C. § 112, second paragraph, as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention." Specifically, the Examiner asserts that the terms "heterologous polynucleotide," "heterologous polypeptide," "heterologous regulatory sequence," "recombinant host cell," and "full-length polypeptide" are vague and indefinite.

Applicants respectfully disagree and traverse this rejection. In analyzing the claims for indefiniteness under 35 U.S.C. § 112, second paragraph, the M.P.E.P. directs that:

> The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:
>
> (A) The content of the particular application disclosure;
> (B) The teachings of the prior art; and
> (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

See M.P.E.P. § 2173.02 (emphasis added).

Applicants submit that, on reading of the instant specification at the time the application was filed, the meaning of all of the referenced terms would have been immediately clear to one of ordinary skill in the art. In particular, the specification clearly gives examples of the heterologous sequences (*see, e.g.*, paragraphs 205-206, 209, 222, 232, 781-782) and describes recombinant host cells (*see, e.g.*, paragraphs 781-782). Moreover, the phrases objected to have been in common usage in the art for many years. Indeed, the instant Examiner has examined and allowed many patents using the identical claim terminology (*see, e.g.*, U.S. Patent No. 4,738,928, claim 5; U.S. Patent No. 6,528,289, claims 2-3 and 7-9; U.S. Patent No. 6,468,765, claims 22-23 and 27-29; U.S. Patent No. 4,775,622, U.S. Patent No. 5,552,301). Applicants submit that, taking the above into account, the language objected to is not indefinite. Accordingly, Applicants respectfully request that the rejection of claims 26-27 and 29-42, under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

III. Rejection of the Claims under 35 U.S.C. §§ 101 and 112, First Paragraph

The Examiner has rejected claims 23-42 under 35 U.S.C. § 101 because the invention is allegedly not supported by either a specific and substantial asserted utility or a well established utility. (*See* Paper No. 10, pages 4-5.) In particular, the Examiner contends that "no information is offered regarding the diagnosis of any particular disease based upon any particular diagnostic assay."

The Examiner has further rejected claims 23-42 under 35 U.S.C. § 112, first paragraph, because one skilled in the art would allegedly not know how to use the claimed invention, based on the supposed lack of either a specific and substantial asserted utility or a well established utility.

Applicants respectfully disagree and traverse these rejections.

A rejection under 35 U.S.C. § 101 is improper when a person of ordinary skill in the art would find credible disclosed features or characteristics of the invention, or statements made by the applicant in the written description of the invention. *See* M.P.E.P. §§ 2107.01(II) – (III) (7th Ed. Rev. 1, Feb. 2000). In addition, an applicant need only make *one* credible assertion of utility for the claimed invention to satisfy 35 U.S.C. § 101. *See, e.g., Raytheon v. Roper,* 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983), *cert. denied,* 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. § 101 is clearly shown."); *see also* M.P.E.P. § 2107.01 at 2100-29; Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (January 5, 2001). Finding a lack of utility is also improper if a person of ordinary skill in the art would know of a use for the claimed invention at the time the application was filed. *See* M.P.E.P. § 2107.01(II)(B); Utility Examination Guidelines at 1098.

Moreover, the Examiner must establish why it is more likely than not that one of ordinary skill in the art would doubt *(i.e.,* "question") the truth of the statement of utility. *See* M.P.E.P. § 2107.01(II)(A); Utility Examination Guidelines at 1098-99. Thus, the Examiner must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. *See id.* The Examiner must also present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the applicants' assertion of utility. *See id.*; *see also In re Brana,* 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). For the reasons set forth below, Applicants respectfully assert that the Examiner has not met the required burden.

In particular, Applicants disagree with the Examiner's assertion that the specification does not relate the claimed polynucleotides to a disease. At paragraphs 79 to 82, the specification teaches that the claimed polynucleotide is expressed in serous papillary adenocarcinoma, and thus can be used as a diagnostic marker and as a chemotherapy target for that cancer. Regardless of the disclosure elsewhere in the specification, an applicant need only make *one* credible assertion of utility for the claimed invention to satisfy 35 U.S.C. § 101.

In view of the above, Applicants respectfully submit that the presently claimed invention possesses specific, substantial, credible, and well-established utilities which constitute patentable utilities under 35 U.S.C. § 101. Because Applicants' assertions of utility are sufficient to satisfy the requirements of 35 U.S.C. § 101, it is respectfully requested that the Examiner's rejection of the claims under 35 U.S.C. § 101 be reconsidered and withdrawn.

Further, the Federal Circuit and its predecessor determined that the utility requirement of 35 U.S.C. § 101 and the how to use requirement of 35 U.S.C. § 112, first paragraph, have the

same basis, *i.e.*, the disclosure of a credible utility. *See In re Brana*, 51 F.3d 1560, 1564, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); *see also* M.P.E.P. § 2107(IV); Utility Examination Guidelines at 1098. As discussed above, the specification teaches specific and well-established utilities of the claimed invention, thereby enabling the skilled artisan to use the claimed polynucleotides. Since the specification teaches how to use the claimed polynucleotides with only routine experimentation and the specification describes specific and immediate utilities for the claimed invention, Applicants submit that the full scope of the claims is enabled. Accordingly, it is respectfully requested that the Examiner's rejection of the claims under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

Conclusion

Entry of the above amendment is respectfully solicited. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the allowance of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an additional extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: November 12, 2003

Respectfully submitted,

By _____

Mark J. Hyman
Registration No.: 46,789
HUMAN GENOME SCIENCES, INC.
9410 Key West Avenue
Rockville, Maryland 20850
(240) 314-1224

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8

1. Fax Cover
2. Fee Transmittal Sheet
3. Petition for an Extension of Time for two months, to and including November 12, 2003
4. Amendment and Response Under 37 C.F.R. § 1.111

I hereby certify that the above-listed correspondence is being facsimile transmitted to the United States Patent and Trademark Office on November 12, 2003.

Mark J. Hyman (Reg. No. 46,789)
Attorney for Applicants

Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, MD 20850
Telephone: (240) 314-1224